

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Steven M. RUBEN

Appl. No.: 10/662,429

Filed: September 16, 2003

For: **Apoptosis Inducing Molecule I**

Confirmation No.: 2663

Art Unit: 1644

Examiner: HUYNH, PHUONG N.

Atty. Docket: 1488.1890003/EJH/SAC

**Declaration of Edward Dul
Ruben Exhibit #30**

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Ruben EXHIBIT #30

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Paper No. _____

Filed on Behalf of Party Ruben:

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES
(Administrative Patent Judge Sally Gardner Lane)

STEVEN M. RUBEN

Junior Party,
(Application No. 08/816,981),

v.

STEVEN R. WILEY
and RAYMOND G. GOODWIN

Senior Party,
(Patent No. 5,763,223).

Patent Interference No. 105,077

DECLARATION OF EDWARD DUL

Ruben EXHIBIT 2030
Ruben v. Wiley et al.
Interference No. 105,077
RX 2030

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DECLARATION OF EDWARD DUL

I, Edward Dul, declare and state as follows:

1. I am employed by GlaxoSmithKline (formerly SmithKline Beecham or "SB") and acted in a scientific role for SB during the time periods discussed below. I have been asked by patent counsel to Human Genome Sciences ("HGS") to describe my activities relating to AIM-I.

2. I performed Western analysis of the AIM-I protein in the weeks leading up to the October 18, 1995 meeting and thereafter under the supervision of SB scientist Edward R. Appelbaum. The objectives of my experiment were to express AIM-I as a fusion protein in *E. coli* for use in raising antibodies, and to express AIM-I in soluble form in *E. coli* or other systems for use in receptor binding and activity assays (RE31). First, plasmid DNA encoding AIM-I was obtained from HGS, purified by Kong B. Tan of SB, and sequenced. Next, the AIM-I coding sequence was subcloned to make two different fusion protein constructs. Purification, sequencing, and construct engineering would have taken at the very least seven days to carry out. Finally, fusion constructs were expressed, and soluble and insoluble fractions of cell lysates and whole cell sonicates were run on a gel dated October 16, 1995 (RE31). I performed a Western blot using antibodies recognizing the AIM-I fusion protein epitope tag on or about October 17, 1995, the results of which were presented at the October 18, 1995 HGS/SB meeting (RE31).

3. On November 17, 1995, I signed five laboratory notebook pages on which I recorded my AIM-I protein expression work (Dul notebook 24098, pages 168-172) (RE32). These pages summarize a portion of my activities directed to AIM-I expression and Western

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blotting that had been conducted over the preceding months, beginning about July 11, 1995 (Dul notebook 24098, page 168) (RE32!).

4. On February 1, 1996, I signed two additional laboratory notebook pages on which I recorded my work relating to AIM-I protein expression, solubility, and detection with various antisera (Dul notebook 24098, pages 180-181) (RE32). These notebook pages show that I imaged a coomassie-stained protein gel on December 14, 1995, and described a Western blot which showed recognition of AIM-I ("purified TL2") with antisera raised at SB (the "CK9B" antisera) and with antisera obtained from HGS (Dul notebook 24098, page 181) (RE32). I obtained a "first bleed" sample of the CK9B antisera from an AIM-I injected rabbit ("TL2 rabbit") and used it to generate the Western blot from the December 14, 1995 gel (Dul notebook 24098, pages 180-181) (RE32). It takes at least about six weeks for an injected rabbit to mount an antibody response, which is typically collected at first bleed for testing, so the rabbit producing the CK9B antisera was injected with AIM-I protein at SB on or about November 1, 1995. Since my experiments demonstrated that the CK9B antisera detected the AIM-I protein, the CK9B rabbit would have been maintained at SB as long as useful antisera was produced, at least until May 1, 1996. I received assistance from at least one other SB scientist, Chris Jones, who purified a one liter induction of AIM-I protein being expressed in *E. coli* ("TL-2-L") (Dul notebook 24098, page 180) (RE32!).

5. On February 8, 1996, I signed one laboratory notebook page describing my work regarding AIM-I protein expression (Dul notebook 24098, page 191) (RE32). On February 9, 1996, I had several laboratory notebook pages relating to AIM-I protein expression reviewed and witnessed (Dul notebook 24098, pages 168-172, 180, 181, and 191) (RE32).

6. On March 5, 1996, I signed six laboratory notebook pages relating to AIM-I expression and antibody work (Dul notebook 24098, pages 193, 194, and 196-199) (RE32). These pages summarize my experiments using bleed 3 of AIM-I antisera CK9B, various AIM-I expression constructs, and various induction temperatures in connection with AIM-I solubility studies. On Sunday, March 3, 1996, I imaged another AIM-I protein gel (Dul notebook 24098, page 198) (RE32). I also received assistance from Seth Fisher of SB in AIM-I protein purification work (Dul notebook 24098, pages 197 and 199) (RE32 !).

7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above-captioned application or any patent issuing thereon.

Date

6/18/04


Edward Dul

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